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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1614	11

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/021,627	Applicant(s) MAX ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-31* is/are pending in the application.

4a) Of the above claim(s) *14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/29/03 has been entered.

Status of Application

Acknowledgement is made of amendment filed on 07/29/03 wherein the request for canceling claims 1-13(claims 1-8 were previously cancelled) and adding new claims 19-31 has been filed and entered properly.

The claims 14-31 are pending and the claims 19-31 that are corresponding to the originally elected invention are presented for the examination whereas the non-elected invention, claims 14-18 are withdrawn.

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is new matter rejection. The claim(s) contains subject matter which was not described in the specification

in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As mentioned in the previous office action(see paper no. 8), applicant can not exclude the limitation if the limitation is not originally included as a part of the invention. In other words, the originally filed disclosure would not have conveyed to one having ordinary skill in the art that applicant had possession of the claimed subject matter(i.e. a di- or tetra-hydrofolic acid containing composition in the absence of vitamin B12) as recited in the claim 19, whereas one skilled in the art would recognize upon reading the specification(see page 16, line 16) that a di- or tetra-hydrofolic acid containing composition can be combined with vitamins such as vitamin B12.

It is especially true when the synergistic combination of folic acid(or its derivatives) and vitamin B12 is already known to one of ordinary skill in the art at the time of the invention was made(see US6011040, col.3, line 11-13). Furthermore, possible presence of vitamin B12 as a part of the claimed invention is readily apparent to the one of ordinary skill when DE A4308282(see the background information of instant specification at page 6, lines 18) is learned, which is incorporated to teach the technical background of the instant invention, see corresponding USpatent(US5496565, col.8, lines 44). Thus, the negative limitation "absence of vitamin B12" recited in claim 1 does not have written descriptive support in the applciaiton disclosure as originally filed within the meaning of 35 USC 112, first paragraph. Thus, the newly added negative

limitation(i.e. in the absence of vitamin B12) is considered to be the" new matter" and the claims are properly maintained as rejected.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim 26 or 30 recites EDTA or BHT, respectively. Although the abbreviated terms(i.e. EDTA or BHT) can be understood in light of the specification, the claim should be clear by itself and should not be confusing in any event. Thus, using parenthetical expression for the abbreviated term along with the full description of the claim tem is acceptable and would obviate this rejection.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S.

patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 19-30 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Russ et al(US 6299890).

Claims are drawn to a topical cosmetic preparation such as oil-in water emulsion or water-in-oil emulsion comprising an oil phase, a water phase and at least one member selected from the group consisting of dihydrofolic acid and tetrahydrofolic acid(0.1-2%).

US'890 teaches an emulsion(e.g. oil-in-water or water-in-oil) makeup composition comprising a water phase, an oil phase and tetrahydrofolic acid(0.01-8%) as a beneficial ingredient, see abstract and column 10, line 42.

All the critical elements required by the dependent claims are also taught by the cited reference. For instance, an emulsion composition (example 1,at col. 11) teaches tocopheryl acetate(0.001%) that is the vitamin E derivative(required by the instant claims 22-23); complexing agent such as EDTA(required by the instant claims 25-26); an inorganic pigment such as titanium dioxide(required by the instant claims 29-30). US'890 further teaches antioxidant such as butylated hydroxytoluene(BHT) required by the instant claims 27-28 at column 10, lines 52-58.

Although tetrahydrofolic acid is not included in the exemplified composition, one would have readily envisaged a cosmetic emulsion composition such as example 1 with tetrahydrofolic acid when Russ(US'890) is learned as a

whole because tetrahydrofolic acid is encompassed by the scope of the patented invention.

Or alternatively, it would have been obvious to one of ordinary skill in the art to make a cosmetic emulsion composition such as example 1 with tetrahydrofolic acid when Russ(US'890) is learned as a whole in view of conventional knowledge because it is conventional wisdom to add beneficial additives to improve the quality of the product in addition to the teaching of US'890 wherein the addition of tetrahydrofolic acid into the patented composition is taught, and skills and techniques for making such composition are also well taught.

It is noted that Russ(US'892) does not teach or suggest vitamin B12 in the patented disclosure. Therefore, one would have either anticipated or expected said composition having tetrahydrofolic acid in the absence of vitamin B12, absent evidence to the contrary.

In any event, the tetrahydrofolic acid containing emulsion composition is not considered to be patentably distinct over the prior art of the record for the reasons set forth above.

6. Claims 19-31 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kellner et al (US 6042815).

US'815 teaches a water and oil emulsion(e.g.oil-in-water emulsion, water-in –oil emulsion, see column 20, lines 27-33) comprising aqueous phase, oil

phase, and **tetrahydrofolic acid**, see abstract, claims and example 1, especially **column 21, lines 27-28**.

Although the patent do not disclose examples with tetrahydrofolic acid listed, it would have been, however, obvious to one of ordinary skill in the art at the time of the invention was made to add tetrahydrofolic acid into the patented composition because the patented disclosure teaches the tetrahydrofolic acid as a beneficial additive to improve the quality of the product, see column 21, lines 20-40.

Thus, one would have been envisaged to do so because it is apparent to add extra skin benefits(e.g. aesthetic and treatment properties, see column 20, lines 36-37) into the patented composition by adding tetrahydrofolic acid. Or alternatively, it would have been obvious to do so because reasonable expectation of success is readily apparent because the cited patent teaches not only techniques and skills required for making such modification but also skin benefits by doing so.

Furthermore, one of ordinary skill in the art to make the patented cosmetic emulsion composition having tetrahydrofolic acid without vitamin B12 because US'815 does not require vitamin B12 in the patent and one would have been motivated do so depending on the consumer's need. Thus, absence of vitamin B12 is fully anticipated and expected from the teaching and examples of the cited reference.

As to claims 20-22, US'815 suggests that an effective amount of tetrahydrofolic acid is about 0.01-8% by weight of the total composition, see column 21, lines 21-22.

As to claims 23-30, US'815 teaches a vitamin E derivative such as tocopheryl acetate in oil-in-water emulsion composition(see example 1), a complexing agent (see column 4, lines 15 thru col. 6, lines 53), an antioxidant such as BHT(butylated hydroxytoluene, see column 21, lines 35-40) and inorganic pigments such as titanium dioxide(see col.19. lines 52 thru col.20, lines 5). All other critical elements are also taught by the cited reference. The skills and techniques required for making the said cosmetic emulsion containing tetrahydrofolic acid are also well taught. Thus the claimed subject matter is not considered to be patentably distinct or obvious over the prior art of the record.

Although specific species(i.e. EDTA) required by the claim 26 is not suggested by the patent, it would have been obvious to one of ordinary skill in the art to substitute complexing agents (taught by US'815) with EDTA because it is conventional knowledge in cosmetic and pharmaceutical art to use EDTA to form a complex with undesirable metal ions as also evidenced by applicant's own admission, for example, at column 5, in lines 14-15 or at column 6, in lines 6-9 of instant specification. It would have been obvious to one of ordinary skill in the art to adopt minor variations such as an addition of beneficial additives(e.g. complexing agent), a titration of optimal dosage regimen or routes of administration, in order to maximize the efficacy and to improve the overall

quality is considered to be well within the skilled level of the artisan, absent evidence to the contrary.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fanger et al(US 6,153,204).

Claim 31 requires hydrodispersion gel.

US'204 teaches a cosmetic or pharmaceutical preparations including hydrodispersion gel, see abstract and example 11(col. 13-14). US'204 teaches folic acid or its derivatives as a beneficial additive such as an anti-oxidant(0.001-30%), see col. 7, lines, 18-63, especially line 43. As suggested in column 7, it would have been obvious to one of oridary skill in the art to make the substitution of an antioxidant included in example 11 with folic acid or folic acid derivatives.

As evidenced by applicant's own admission(see the instant specification at page 4, lines 13-14), the term "derivatives of folic acid" is readily understood as meaning, in particular, dihydrofolic or tetrahydrofolic acid as well as seen in the example 8 at page 21.

One would have been motivated to make such hydrodispersion gel containing folic acid derivatives such as dihydro- or tetrahydrofolic acid because it is always desired to have different formulations to fit consumer's need and preference where the consumer's compliance and satisfaction is directly proportional to the overall quality of the treatment.

It is conventional wisdom to add beneficial additives to improve the quality of the product in addition to the teaching of US'204 wherein the addition of tetrahydrofolic acid into the patented composition is suggested, and skills and techniques for making such composition are also well taught.

The teaching of the cited reference is particularly pertinent to the applciant's concern. Thus, the claimed subject matter is not patentably distinct over the prior art of the record.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this

application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Primary Patent Examiner
October 24, 2003
Art unit 1614